

HFI-SS (P...)
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service 514
Food and Drug Administration

Refer to: CFN 1125009

Baltimore District
900 Madison Avenue
Baltimore, Maryland 21201
Telephone: (410) 962-4040

August 7, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Carol Johnson
1215 Deer Park Road
Westminister, Maryland 21157

Dear Mr. Johnson:

An investigation at your beef operation located in Westminister, Maryland was conducted on June 23, 1997, by a representative of the State of Maryland under contract to the Food and Drug Administration. The investigation confirmed that you offered a steer for sale for slaughter as human food that contained an illegal drug residue. This causes such food to be adulterated within the meaning of Sections 402(a)(2)(D) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). In addition, you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5).

On or about May 22, 1997, you sold a steer identified as originating from your premises, for slaughter as human food, at [REDACTED] USDA/FSIS analysis of tissues collected from that animal disclosed the presence of 61.00 parts per million (ppm) and 40.00 ppm of the drug Sulfamethazine in the liver and muscle tissues, respectively. A tolerance of 0.10 ppm has been established for residues of Sulfamethazine in the edible tissues of cattle (Title 21, Code of Federal Regulations, Section 556.670). The presence of this drug in edible tissues from this animal causes the food to be adulterated. You should have received a letter dated June 3, 1997, from USDA concerning this matter.

The investigation found that you hold animals under conditions that permit those bearing potentially harmful drug residues to enter the food supply. For example, you lack an adequate system for assuring that drugs are used in accordance with directions contained in the labeling; that medicated animals have been identified; and that medicated animals have been withheld from slaughter for appropriate periods of time to permit depletion of potentially hazardous residues of drugs from edible tissues. Foods from animals held under such conditions are adulterated.

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You are adulterating the drug Sulfamethazine that your farm uses on cattle within the meaning of Section 501(a)(5) of the Act when you fail to use the drug in conformance with its approved labeling. Your use of the drug without following the labeled withdrawal period causes the drug to be unsafe.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

The violations listed above are not intended to be an all-inclusive list. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken and/or plan to take to prevent further violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Your reply should be sent to the Food and Drug Administration, Richmond Resident Post, 10710 Midlothian Turnpike, Suite 424, Richmond, Virginia 23235, to the attention of Scott J. MacIntire, Compliance Officer. Mr. MacIntire can be reached at 804-379-1627, ext. 14.

Sincerely,



Elaine Knowles Cole

Director, Baltimore District

Mr. Carol Johnson

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cc: USDA/FSIS
Northeastern Region
Mellon Independence Center
701 Market St., 2-B South
Philadelphia, PA 19106-1576

cc: Maryland Department of Agriculture
Animal Health
50 Harry S. Truman Parkway
Annapolis, Maryland 20742